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No. _____

In The

Supreme Court of the United States

NARENDRA M. PATEL, M.D.,

Petitioner,

v.

TOMMY G. THOMPSON, et al.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED FOR REVIEW

1. Was the Secretary's election to apply retroactively to Dr. Patel the harsher October 1998 version of 42 C.F.R. § 1001.102 (rather than the less harsh 1992 version of 42 C.F.R. § 1001.102 in effect at the time of the events leading to Dr. Patel's exclusion and in effect when the Secretary started exclusion proceedings against Dr. Patel) a *punitive* application of that harsher regulation or of its underlying statute 42 U.S.C. § 1320a-7 (a mandatory exclusion statute which produces both (a) punitive effects on the excluded physician and (b) for a period of time unmeasured by ascertainable standards, potentially remedial effects for federal health programs) in violation of the *Ex Post Facto* Clause of the United States Constitution?

PARTIES

A. Petitioner

1. Narendra M. Patel, M.D.

B. Respondents

1. Tommy G. Thompson, Secretary, United States, Department of Health and Human Services
2. Janet Rehnquist, Inspector General, United States Department of Health and Human Services

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OPINIONS AND ORDERS BELOW

a. *Narendra M. Patel v. Tommy G. Thompson, et al.*, 319 F.3d 1317 (11th Cir. Jan. 31, 2003)

b. *Narendra M. Patel v. Tommy G. Thompson, et al.*, United States District Court, Northern District of Georgia, Civil Action File No. 4:00-CV-0277-HTML (Jul. 3, 2002)

STATEMENT OF JURISDICTION

Subject matter jurisdiction exists over Dr. Patel's exclusion from federal health care programs pursuant to 42 U.S.C. § 1320a-7(f) and other applicable law. This Court has appellate jurisdiction, pursuant to 28 U.S.C. § 1254(1), to review the decision of the Court of Appeals for the Eleventh Circuit. The Court of Appeals entered Judgment for the Secretary on January 31, 2003, and the Petitioner filed a timely Petition for Writ of Certiorari on May 1, 2003. Rules of the Supreme Court 13.

U.S. CONSTITUTIONAL PROVISIONS, TREATIES, STATUTES, RULES AND REGULATIONS INVOLVED

U.S.C.A. Const. Article 1, § 9, cl. 3. (*Ex Post Facto* Clause)

42 U.S.C. § 1320a-7

42 C.F.R. § 1001.102

5 U.S.C. § 706(2)(A)

STATEMENT OF THE CASE

Plaintiff, Narendra M. Patel (hereinafter "Dr. Patel"), appeals a final decision of the Eleventh Circuit Court of Appeals. This appellate court upheld a final decision of the United States District Court, Northern District of Georgia, Rome Division. This trial court upheld a final decision of the Appellate Division of the Departmental Appeals Board (hereinafter "DAB") of the United States Department of Health and Human Services (hereinafter "HHS"). The DAB upheld a decision of an Administrative Law Judge, who in turn had upheld a decision of the Inspector General of HHS (hereinafter "IG"), to exclude Dr. Patel from participation in Medicare, Medicaid and all federal health care programs (hereinafter "Federal Health Programs") for a total of ten years. The IG's ten year exclusion of Dr. Patel consists of (a) a mandatory exclusion of five years for a certain June 16, 1997 conviction, and (b) an additional five years which the IG decided in the IG's discretion to impose for two specific "aggravating factors." The two specific aggravating factors became effective on October 2, 1998, when 42 C.F.R. § 1001.102(b) was amended ("October 1998 Regulations"). The October 1998 Regulations gave the IG certain discretion, if a mandatory exclusion already applied, to impose additional periods of exclusion based on new "aggravating factors" ("New Aggravating Factors") first specified in the October 1998 Regulations. The aggravating factors ("Original Aggravating Factors") set forth in the 1992 version of 42 C.F.R. § 1001.102(b) (the "1992 Regulations") did not set forth the specific aggravating factors which the IG used retroactively to double Dr. Patel's period of exclusion from five years to ten years.

Accordingly, Dr. Patel argues that the Secretary's retroactive use of the October 1998 Regulations "New Aggravating Factors" to so drastically enlarge Dr. Patel's period of exclusion (without any articulation of a standard of why a shorter period of exclusion would not be equally remedial) was substantially more punitive than remedial and therefore violated the *Ex Post Facto* Clause.

Although (a) the exclusion process began on June 12, 1998, (b) all pertinent actions occurred prior to that date, and (c) the IG could have issued an exclusion decision based on the less harsh 1992 Regulations prior to the date of the October 1998 Regulations, the IG did not issue the decision on the discretionary additional exclusion until October 30, 1998, by which time New Aggravating Factors had been promulgated in the October 1998 Regulations.

In reviewing this matter, the Eleventh Circuit Court of Appeals below observed that:

> This [Eleventh Circuit] Court has held, however, that the exclusionary periods provided by the statute 42 U.S.C. § 1320a-7 are remedial, not punitive, and therefore are not precluded from retroactive application by a governmental agency. *See Manocchio v. Kusserow*, 961 F.2d 1539, 1543 (11th Cir. 1992) (holding that § 1320a-7 is "not punitive, but rather remedial in nature and purpose"). Since the statute itself has been held to be remedial, the regulations regarding exclusion are *a fortiori* remedial.

Patel v. Thompson, et al., 319 F.3d 1317, 1319 (11th Cir. 2003); *see also Kahn v. Inspector General of U.S. Dept. of Health and Human Services*, 848 F. Supp. 432, 437 (S.D. N.Y. 1994) (also finding that 42 U.S.C. § 1320a-7 is

remedial, but not discussing regulations promulgated to implement 42 U.S.C. § 1320a-7).

Manocchio examined the intent of Congress in enacting 42 U.S.C. § 1320a-7, and found that Congress intended the statute to be remedial. 961 F.2d at 1542. However, in Dr. Patel's case, neither the district court nor the appeals court below separately examined whether the regulations, *as applied*, reflect only remedial intent, as opposed to both punitive and remedial effect.

In addition to the question of whether the statute 42 U.S.C. § 1320a-7 is remedial when examined by its effects, separate questions exist as to (a) whether regulations promulgated under the aegis of 42 U.S.C. § 1320a-7 are actually punitive or remedial and (b) in the case, as here, where there is a choice between two competing regulations promulgated under 42 U.S.C. § 1320a-7, whether a *choice* of a harsher, retroactively applied regulation is a *punitive application* of an otherwise potentially remedial regulation.

ARGUMENT

A. BACKGROUND

1. 42 U.S.C. § 1320a-7

Title 42, U.S.C. § 1320a-7 (also known as Section 1128(a)(2) of the Social Security Act) hereinafter sometimes referred to as "Section 1128(a)(2)", mandates that the Secretary of Health and Human Services (hereinafter "Secretary") exclude:

> [a]ny individual or entity that has been convicted, under Federal or State law, of a criminal

> offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service.

Such a mandatory exclusion must be for not less than five years. Section 1128(c)(3)(B) of the Act; 42 U.S.C. § 1320a-7(c)(3)(B); *see also* 42 C.F.R. § 1001.102(a).

2. Regulations Controlling Discretion to Lengthen Mandatory Exclusion Period

The mandatory five year exclusion period may be lengthened at the IG's reasonable discretion if certain aggravating factors exist. 42 C.F.R. § 1001.102(b). If the five year mandatory exclusion applies to Dr. Patel, then whether Dr. Patel may be excluded for additional time depends upon whether the 1992 or the 1998 version of 42 C.F.R. § 1001.102(b) controls.

3. 1992 Version

Effective January 29, 1992, 42 C.F.R. § 1001.102(b) provided for six aggravating factors ("Original Aggravating Factors"). None of the Original Aggravating Factors apply to Dr. Patel.

4. October 1998 Version

Effective October 2, 1998, 42 C.F.R. § 1001.102(b) was amended to add the two New Aggravating Factors as follows:

> (b)(4) In convictions involving patient abuse or neglect, the action that resulted in the conviction . . . consisted of non-consensual sexual acts;

. . .

> (b)(8) Whether the individual or entity . . . has been the subject of any other adverse action by any Federal, State, or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for imposition of the exclusion.

These two New Aggravating Factors were applied retroactively by the IG to Dr. Patel to increase his exclusion period to ten years.

B. THE OCTOBER 1998 REGULATIONS DO NOT APPLY TO DR. PATEL

Under the 1992 Regulations, none of the Original Aggravating Factors applied to Dr. Patel. The IG made no findings that any of the Original Aggravating Factors applied to Dr. Patel, and therefore, on the basis of the record of findings in this case applicable to the 1992 Original Aggravating Factors, the IG had no basis to lengthen Dr. Patel's mandatory exclusion period.

Applying the October 1998 Regulations to Dr. Patel violates the anti-retroactivity principle well established in law. First, the October 1998 Regulations do not by their terms apply retroactively. Second, applying the October 1998 Regulations to Dr. Patel results in a significant increase in his liability based on conduct and actions occurring before the effective date of the October 1998 Regulations, in violation of the *Ex Post Facto* Clause of the United States Constitution and applicable law against punitive retroactive applications of regulations.

Even if the October 1998 Regulations apply to Dr. Patel, the IG's decision to lengthen Dr. Patel's exclusion by

five years is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, because there is no evidence that an additional five years is necessary to remediate Dr. Patel or to protect federal health programs and their beneficiaries.

C. THE OCTOBER 1998 REGULATIONS DO NOT APPLY TO DR. PATEL BECAUSE OF THE ANTI-RETROACTIVITY PRINCIPLE OF LAW

1. Background of the Law

In *Landgraf v. USI Film Products*, 511 U.S. 244 (1994), the Supreme Court addressed the issue of retroactivity and framed the issue as:

> Thus, the controlling question is whether the Court of Appeals should have applied the law in effect at the time the discriminatory conduct occurred, or at the time of its decision in July 1992. Id. at 250.

The Supreme Court held that the law in effect at the time the discriminatory conduct occurred is the applicable law. In reaching its decision, the Supreme Court noted that:

> federal courts have labored to reconcile two seemingly contradictory statements found in our decisions concerning the effect of intervening changes in the law. Each statement is framed as a generally applicable rule for interpreting statutes that do not specify their temporal reach. The first is the rule that 'a court is to apply the law in effect at the time it renders its decision.' The second is the axiom that '[r]etroactivity is not favored in the law,' and its interpretive corollary that 'congressional enactments and administrative rules will not be construed to have

> retroactive effect unless their language requires this result.' Id. at 263-264. [citations omitted.]

The Supreme Court summarized how a court should deal with the apparent tension between these two rules as follows:

> When a case implicates a federal statute enacted after the events in suit, the court's first task is to determine whether Congress has expressly prescribed the statute's proper reach. If Congress has done so, of course, there is no need to resort to judicial default rules. When, however, the statute contains no such express command, the court must determine whether the new statute would have retroactive effect, *i.e.*, whether it would impair rights a party possessed when he acted, *increase a party's liability for past conduct,* or impose new duties with respect to transactions already completed. If the statute would operate retroactively, our traditional presumption teaches that it does not govern absent clear congressional intent favoring such a result. Id. at 280 [emphasis added].

The Supreme Court then applied the foregoing statement of the law to the facts in *Landgraf*, and reasoned that the law in effect *at the time of the conduct* should apply.

2. Applying *Landgraf* to this Case

Applying the law and rationale of *Landgraf* to the facts of this case leads to the inescapable conclusion that the 1992 Regulations in effect *at the time of Dr. Patel's conduct and at the time of the June 12, 1998 Exclusion Notice* should be applied. *Landgraf* first instructs a court

to consider whether there is any clear expression of congressional intent that the October 1998 Regulations should have retroactive effect. There is no such expression. In fact, the New Aggravating Factors in the October 1998 Regulations were simply added by the HHS upon its discretion, and not because of any congressional legislation. 63 F.R. 46676 (September 2, 1998) at 46677.

In the absence of any clear congressional expression, *Landgraf* next instructs a court to determine whether the October 1998 Regulations would (a) impair rights a party possessed when he acted, *(b) increase a party's liability for past conduct*, or (c) impose new duties with respect to transactions already completed. *Landgraf* at 280. The IG's retroactive application of the October 1998 Regulations to Dr. Patel increased Dr. Patel's liability for past conduct, because without applying the New Aggravating Factors to Dr. Patel, his exclusion period would have been five years (*i.e.*, the mandatory exclusion period). Applying the New Aggravating Factors to Dr. Patel results in a ten year exclusion. *Landgraf* instructs that under these circumstances, "our traditional presumption teaches that it [the later rule] does not govern absent clear congressional intent favoring such a result." *Id.* at 280.

3. Other Case Law Support for Dr. Patel

Other cases are equally persuasive in favor of Dr. Patel's position.

For example, in *Covey v. Hollydale Mobilehome Estates*, 116 F.3d 830 (9th Cir. 1997), the Ninth Circuit, citing *Landgraf*, held that new HUD regulations did not apply to defendant's past conduct because "all the events

at issue occurred before the [new] HUD regulations took effect." *Id.* at 835.

Similarly, in *Carpenters District Council of New Orleans & Vicinity v. Dillard Dept. Stores, Inc.*, 15 F.3d 1275 (5th Cir. 1994), in deciding whether to apply final WARN Act regulations in effect when the District Court made its decision or proposed regulations in effect at the time of the defendant's conduct, the Fifth Circuit held that the proposed regulations in effect at the time of defendant's conduct govern, "[b]ecause administrative rules should not be construed as having retroactive effect unless their language requires that result . . . " *Id.* at 1291.

All of the events in Dr. Patel's case (namely, the alleged conduct, the conviction and the June 12, 1998 Exclusion Notice) occurred *before the October 1998 Regulations when the New Aggravating Factors took effect.* Applying *Landgraf*, *Covey* and *Carpenters District Council* to Dr. Patel's facts, the 1992 Regulations in effect at the time of Dr. Patel's conduct should be applied, not the October 1998 Regulations.

4. The Date of the Secretary's Decision Does Not Determine Which of the Two Regulations Apply

The Secretary has argued below that the October 1998 Regulations were not retroactively applied to Dr. Patel because at the time of the IG's decision, the IG applied the regulations then in effect.

The fact that the IG's decision was made after the October 1998 Regulations became effective, taken alone, does *not* answer the question before this Court. Dealing

with a retroactivity issue necessarily means addressing whether the law in effect at the time of a decision (for example, a decision by an administrative agency or a court) is applicable, or whether the law in effect at the time of the relevant past conduct applies. This issue is not decided based upon *when* the IG dated her decision, particularly since the IG controls the timing of when her decision is dated.

In Dr. Patel's case, the IG's process of determining aggravating factors began on or before the June 12, 1998 Exclusion Notice and could have been decided on the basis of Dr. Patel's August 21, 1998 response prior to October 2, 1998 when New Aggravating Factors became part of federal regulations. This issue is determined by which law governs the case regardless of when the IG dates her decision. The choice of which law governs the case, as *Landgraf* teaches, is decided by considering the nature of the retroactive effect upon Dr. Patel. As the Supreme Court aptly stated in *Landgraf*:

> The conclusion that a particular rule operates 'retroactively' comes at the end of a process of judgment concerning the nature and extent of the change in the law and the degree of connection between the operation of the new rule and a relevant past event.

Id. at 270.

At the time of Dr. Patel's conduct and at the time of his plea, the IG did not have specific aggravating factors applicable to Dr. Patel. Therefore, the IG lacked authority under the 1992 Regulations, based on aggravating factors, to impose an exclusion longer than the minimum. The 1992 Regulations clearly provide in 42 C.F.R. § 1001.102(b) the

factors that may be the "basis for lengthening the period of exclusion." None of the Original Aggravating Factors apply to Dr. Patel.

The court below found that the exclusion statute, and its regulations *a fortiori* are in the nature of remedial prospective relief to further the purposes of the Medicare program, rather than a punitive measure. The Supreme Court in *Landgraf* rejected this same type of argument, when it said "[i]t will frequently be true, as petitioner and *amici* forcefully argue here, that retroactive application of a new statute would vindicate its purpose more fully. That consideration, however, is not sufficient to rebut the presumption against retroactivity." *Id.* at 285-286.

The test is whether the October 1998 Regulations impose "additional burdens based on conduct that occurred in the past." *Id.* at 283, fn. 35. When Dr. Patel elected to plea bargain *nolo* to the charge against him, the mandatory exclusion period was five years. The alleged sexual conduct was not an Original Aggravating Factor under the 1992 Regulations that triggered the IG's discretion to lengthen the mandatory exclusion. At the time of Dr. Patel's *nolo* decision as well as at the time the IG commenced exclusion proceedings against Dr. Patel, and in the absence of the IG's finding that the act resulting in Dr. Patel's conviction had "significant adverse physical, mental or financial impact on one or more program beneficiaries" (42 C.F.R. § 1001.102(b)(3)), there was no threat that his penalty would exceed five years.

5. Because the 1998 Regulations Increased Dr. Patel's Liability, They May Not Be Applied Retroactively

The bottom line of whether the application of the October 1992 Regulations is impermissibly retroactive lies in the answer to the legally controlling (based on *Landgraf*) question: *Do the October 1998 Regulations increase Dr. Patel's liability for conduct that occurred before the October 1998 Regulations were effective?* The answer is yes, because Dr. Patel's Medicare exclusion is ten years under the October 1998 Regulations instead of five years under the 1992 Regulations. Thus, the decision below must be reversed pursuant to the governing law stated in *Landgraf* because Dr. Patel's liability was increased for conduct that occurred before the October 1998 Regulations were effective.

D. EVEN IF THE OCTOBER 1998 REGULATIONS APPLY TO DR PATEL, THE IG'S DECISION TO LENGTHEN DR. PATEL'S EXCLUSION BY FIVE YEARS IS ARBITRARY, CAPRICIOUS, AND AN ABUSE OF DISCRETION

Under the Administrative Procedure Act, 5 U.S.C. § 706(2)(A), a reviewing court shall "set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." In order to avoid judicial reversal of its action as arbitrary, capricious, or an abuse of discretion, an agency must "articulate a 'rational connection between the facts found and the choice made.'" *Bowman Transportation, Inc. v. Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 285 (1974) [citations omitted].

Here neither the Secretary nor the courts below have (a) made any factual findings about the likelihood (or lack thereof) of Dr. Patel committing non-consensual sexual contact again with a patient and the time dimensions of remedies reasonably necessary to insure future patient safety or (b) articulated a rational connection between facts found and why an additional five years of exclusion must be added to the initial mandatory five years.

The IG relied upon the two New Aggravating Factors in lengthening Dr. Patel's exclusion by five years. One factor related to Dr. Patel surrendering his California license based upon the Georgia Medical Board's action. This is *not* a separate "aggravating factor" under the October 1998 Regulations, because it is based upon the exact same alleged facts as Dr. Patel's Georgia license suspension. While admittedly the language of 42 C.F.R. § 1001.102(b)(8) [now § (b)(9) under the current regulations] is unclear, the Secretary described its intent as follows:

> The intent of the revised language is to allow the OIG to increase the length of exclusion if an individual or entity was convicted of *other* offenses at the same time as he or she was convicted of the offense that served as the basis for the exclusion. Inclusion of this aggravating factor will permit the OIG to increase a length of exclusion when an individual is convicted of Medicare fraud and any *other* offense, such as drug distribution or income tax evasion. The aggravating factor will take into consideration separate and different types of convictions that occurred concurrently; *we do not intend to use the basis of the OIG exclusion more than once as a factor in lengthening an exclusion.*

63 F.R. 46676 at 46681. [emphasis added] Moreover, if this is a separate aggravating factor, as discussed below regarding the IG's arbitrary, capricious, and abuse of discretion decision, the IG has shown no rational connection between the existence of this factor and why it is necessary to apply another five years to achieve remediation.

Therefore, the IG is left with only *one* aggravating factor – which is a *single, isolated* case of a misdemeanor sexual battery charge (*i.e.*, inappropriate touching of breast). Faced with this same evidence of a single, isolated act and findings of the state's psychiatrist, the Georgia Medical Board suspended Dr. Patel's license for six months subject to five years probation, and required that Dr. Patel undergo psychiatric examinations, counseling sessions, and other remedial actions. The Georgia Medical Board used their prior experience in such matters, a state psychiatrist's assessment of Dr. Patel, applied a plan of remedial treatment, and judged that Dr. Patel could return to practicing medicine after six months subject to probation.

There is no evidence whatsoever that the IG applied any kind of reasoned approach similar to the Georgia Medical Board to address an appropriate remedial period for Dr. Patel to be excluded from Medicare. In light of Dr. Patel's having completed the plan of treatment prescribed by the Georgia Medical Board, there is no evidence that beneficiaries of federal health programs need to be protected from Dr. Patel by lengthening Dr. Patel's exclusion.

E. BECAUSE THE IG'S CHOICE OF THE HARSHER OF THE TWO VERSIONS OF THE REGULATION IS A PUNITIVE CHOICE AND BECAUSE THE REGULATION'S EFFECT IS PUNITIVE IN PART, DR. PATEL SHOULD BE PROTECTED FROM RETROACTIVE APPLICATION OF THE OCTOBER 1998 REGULATION

The court below noted that it has held that the mandatory exclusion provisions of 42 U.S.C. § 1320a-7 are remedial, and thus in the absence of facts showing non-remedial application, the *Ex Post Facto* Clause of the United States Constitution are not applicable to 42 U.S.C. § 1320a-7. *Manocchio v. Kusserow*, 961 F.2d 1539 (11th Cir. 1992). However, where (as in Dr. Patel's case) the discretionary exclusion provisions of 42 C.F.R. § 1001.102(b) are applied arbitrarily with enhanced severity so that there was punitive effect on Dr. Patel as well as remedial effect for federal health programs, then punitive effect exists. While the application of the 1992 Regulation is in part remedial, its accompanying punitive effect violates the *Ex Post Facto* Clause of the United States Constitution. U.S.C.A. Const. Article 1, § 9, cl. 3. The manner in which 42 C.F.R. § 1001.102(b) has been applied to Dr. Patel is punitive (in that there is no showing that the ten year exclusion in Dr. Patel's case is not far in excess of time required for protection of the public or remediation of Dr. Patel), and thus the *Ex Post Facto* Clause has been violated. The facts of this case illustrate that *ex post facto* implementation of regulations is as pernicious as *ex post facto* legislation.

CONCLUSION

Under the facts and record of this case, Dr. Patel's Medicare exclusion should be for the mandatory five years only, because of no finding that any of the 1992 Original Aggravating Factors applied. The Secretary's choice to wait to apply a harsher regulation, and to apply that regulation retroactively to lengthen Dr. Patel's exclusion to ten years, is punitive, is inherently unfair, and in violation of law under the anti-retroactivity principle, and because the IG's decision is arbitrary, capricious, and an abuse of discretion, it is punitive. Therefore, the use of the October 1998 Regulations is punitive and in violation of the *Ex Post Facto* Clause. Accordingly, the Secretary's actions in this case leading to the exclusion of Dr. Patel for more than the statutory minimum of five years should be held invalid.

Respectfully submitted,

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II. Other Relevant Opinions, Orders, Findings of Fact and Conclusions of Law:

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[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 02-14821
Non-Argument Calendar

D.C. Docket No. 00-00277-CV-HLM-4

NARENDRA M. PATEL, M.D.,

Plaintiff-Appellant,

versus

TOMMY G. THOMPSON, Secretary of
the Department of Health and Human Services,
JANET RENQUIST [sic], Inspector General of
the Department of Health and Human Services,

Defendants-Appellees.

Appeal from the United States District Court
for the Northern District of Georgia

(Filed January 31, 2003)

Before BARKETT, HULL and RONEY, Circuit Judges.

PER CURIAM:

Appellant Dr. Narendra M. Patel appeals the district court's affirmance of the Department of Health and Human Services' ("HHS") decision to exclude his participation in all federal health programs for a period of ten years. Dr. Patel argues, *inter alia,* that the two aggravating factors

relied upon by the HHS had an impermissible retroactive effect and thus should not have been utilized to exclude him beyond the mandatory five year exclusion period provided by 42 U.S.C. § 1320a-7(c)(3)(B). After careful review and in accord with this Court's decision in *Manocchio v. Kusserow,* 961 F.2d 1539 (11th Cir. 1992), we affirm, holding that the district court properly determined that the suspension by the HHS is remedial and not subject to retroactive application restrictions established by law.

On June 16, 1997, Dr. Patel pleaded *nolo contendere* to one count of sexual battery in Georgia state court. The sexual act occurred during a medical appointment with a female patient on August 20, 1996. On June 12, 1998, the HHS notified Dr. Patel that he would be excluded from participating in federally-funded medical programs for a statutory minimum of five years, and that the exclusion period could be increased if aggravating factors were identified. On October 30, 1998, the HHS then notified him that two aggravating factors were present and that his exclusion period would be extended five additional years, for a total of ten years. Specifically, the HHS increased the exclusion period based on findings that Patel (1) engaged in a non-consensual sexual act with a patient and (2) his medical license was revoked by both Georgia and California based on the same inappropriate conduct with his patient. The ten year exclusion was affirmed by an administrative law judge and a subsequent administrative appellate court, both finding the exclusion appropriate and reasonable.

Dr. Patel makes three arguments: *first,* he argues that the five year mandatory exclusion set forth in 42 U.S.C. § 1320a-7(c)(3)(B) is inapplicable because there was insufficient evidence to show that his sexual misconduct

was "in connection with the delivery of a health care item or service," and, *second,* he argues that the HHS's findings, which were affirmed by the district court, were based on insufficient evidence. After careful review of the briefs, record, and applicable law, we find these arguments to be without merit.

The *third* issue is whether the HHS improperly applied the 1998 amendment to the regulations, 42 C.F.R. § 1001.102, which became effective on October 2, 1998, since his conduct occurred prior thereto, in 1996. The 1998 regulations added additional aggravating factors that the HHS "may" consider when increasing an exclusion beyond the five year statutory mandatory minimum exclusion. *See* 42 C.F.R. § 1001.102(b) (1998). In extending Patel's exclusions from participating in federal health programs to ten years, the HHS relied on the two aggravating factors which were the 1998 regulations added to the factors that the agency "may" consider as bases for an extended period of exclusion:

> (b)(4) In convictions involving patient abuse or neglect, the action that resulted in the conviction . . . consisted of non-consensual sexual acts;
>
> . . .
>
> (b)(8) Whether the individual or entity . . . has been the subject of any other adverse action by any Federal, State, or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for imposition of exclusion.

Id.

Dr. Patel argues that application of these 1998 additions was improper because they were not put in the

regulations until *after* his 1996 conduct and thus created an impermissible increase of his liability in "violation of law under the anti-retroactivity principle."

This Court has held, however, that the exclusionary periods provided by the statute 42 U.S.C. § 1320a-7 are remedial, not punitive, and therefore are not precluded from retroactive application by a governmental agency. *See Manocchio v. Kusserow,* 961 F.2d 1539, 1543 (11th Cir. 1992) (holding that § 1320a-7 is "not punitive, but rather remedial in nature and purpose"). Since the statute itself has been held to be remedial, the regulations regarding exclusion are *a fortiori* remedial.

Dr. Patel argues that *Landgraf v. USI Film Products,* 511 U.S. 244 (1994), precludes application of the 1998 additions. In *Landgraf,* a case involving Title VII of the Civil Rights Act of 1964, the Court held that the 1991 Amendments to the Act which created a right to recover compensation and punitive damages for employment discrimination could not be applied retroactively because the statute would "attach an important new legal burden" to a Title VII defendant's conduct. *Id.* at 283. The retroactive concerns raised in *Landgraf* do not apply to the facts and circumstances of this case and do not change the *Manocchio* analysis. Our decision in *Manocchio* explains that § 1320a-7, the underlying statute to 42 C.F.R. § 1001.102(b), is *prospective* and intended to protect current and future federal medical program recipients from "abusers of these programs." *Manocchio,* 961 F.2d at 1542. As such, the retroactive application concerns stated in *Landgraf* simply do not run contrary to the proactive nature of the application of § 1001.102 in this case.

We note, also, that no meritorious argument has been made that Dr. Patel's conduct with his patient could *not* have given rise to an extended exclusion period prior to the 1998 additions that the HHS relied upon.

AFFIRMED.

United States Court of Appeals
For the Eleventh Circuit

No. 02-14821

District Court Docket No.
00-00277-CV-HLM-4

NARENDRA M. PATEL, M.D.,

Plaintiff-Appellant,

versus

TOMMY G. THOMPSON,
Secretary of the Department
of Health and Human Services,
JANET RENQUIST [sic],
Inspector General of the
Department of Health
and Human Services,

Defendants-Appellees.

Appeal from the United States District Court
for the Northern District of Georgia

JUDGMENT

(Filed January 31, 2003)

It is hereby ordered, adjudged, and decreed that the attached opinion included herein by reference, is entered as the judgment of this Court.

Entered: January 31, 2003
For the Court: Thomas K. Kahn, Clerk
By: Gilman, Nancy

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ROME DIVISION

Narenda M. Patel,

Plaintiff,

v.

CIVIL ACTION FILE
NO. 4:00-CV-0277-HLM

Tommy G. Thompson, Secretary, United States Department of Health and Human Services, and Janet Rehnquist, Inspector General, United States Department of Health and Human Services,

Defendants.

ORDER

(Filed Jul. 3, 2002)

This case involves Plaintiff's appeal from a final decision of the Secretary of the Department of Health and Human Resources [sic] that excluded Plaintiff from participating in Medicare, Medicaid, and all other federally funded healthcare programs as a healthcare provider for a minimum period of ten years. The case is before the Court on Plaintiff's Motion to Supplement the Administrative Record [16], Plaintiff's Motion to Supplement the Administrative Record [17], the Report and Recommendation of United States Magistrate Judge Gerrilyn G. Brill [23], Plaintiff's Objections to the Report and Recommendation [24], and Defendants' Response to Plaintiffs' [sic] Objections to the Report and Recommendation [27].

I. Motions to Supplement the Record

Plaintiff has requested permission to supplement the administrative record with a letter dated June 12, 1998, which was sent to Plaintiff from the Secretary's Assistant Regional Inspector General (the "June 12, 1998, letter"). Plaintiff also seeks permission to add a letter dated August 21, 1998, which was sent by Plaintiff's counsel to the Secretary's Regional Inspector General for Investigations (the "August 21, 1998, letter). The August 21, 1998, letter includes arguments and supporting evidence consisting of letters submitted on Plaintiff's behalf, opposing Plaintiff's exclusion from participation in federally-funded healthcare programs. Defendant opposes both Motions.

The Court agrees with Judge Brill that supplementing the Record to include the June 12, 1998, letter is appropriate. (Report and Recommendation at 9-10.) The Court therefore grants Plaintiff's Motion to Supplement the Record with the June 12, 1998, letter.

The Court also agrees with Judge Brill that the August 21, 1998, letter does not provide the Court with any useful information that is not otherwise contained in the record. (Report and Recommendation at 10.) The Court therefore denies Plaintiff's Motion to Supplement the Record with the August 21, 1998, letter.[1]

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[1] In any event, the August 21, 1998, letter and its attached exhibits would not affect the Court's ruling in this case.

II. Background

Plaintiff resides in Dalton, Georgia. Plaintiff is a licensed physician specializing in gastroenterology. Plaintiff practices in the Dalton area.

On August 21, 1996, K.T.,[2] a patient of Plaintiff's, submitted a sworn and notarized statement to the Board of Medical Examiners for the State of Georgia ("Georgia Board of Medical Examiners"). (Admin. Rec. App. A at 331.) In that statement, K.T. stated that during a medical appointment that K.T. had with Plaintiff on August 20, 1996, Plaintiff placed his mouth on K.T.'s breast and inappropriately touched her genitals. (*Id.*) K.T.'s statement provided, in relevant part:

> I suffer from Chrons Disease. I had an appointment for a check up with my doctor, Narenda [sic] Patel[,] on August 20, 1996 at 11:00 a.m. While examining me, he asked me if I had any chest pain. I did not understand why he asked that question because my disease [a]ffects my gastrointestinal system. However, I said no but, I told him I did have a lump in my left breast. I told him that I had the lump checked by a nurse who came to our apartment complex in the healthmobile and she said that it was all right. I have had a similar lump before and it went away. He decided to examine the lump and tried to unclasp my bra. There was no one in the room with us but, he was my doctor and I trusted him so I was not worried about that. He had trouble

[2] To protect the alleged victim's privacy, the Court will refer to the alleged victim by her initials.

> with the clasp so I undid it. He started to examine the lump. Then, he put his mouth over my nipple. I did not know what to say or do. I was very upset and embarrassed. After I left his office, I started thinking about what happened. Before the breast exam, he had been pushing on my stomach to see if I felt any pain in my colon. [W]hile doing this, he performed a pelvic exam with no one in the room. He did not have gloves on when he did this exam and he did put his finger in my vagina.

(*Id.*)

A grand jury sitting in the Superior Court of Whitfield County, Georgia, indicted Petitioner for sexual battery. The indictment charged, in relevant part, that on or about August 20, 1996, Plaintiff "did intentionally make physical contact with the intimate parts of the body, to wit: breasts, of another female person, to wit: [K.T.], without the consent of [K.T.], by placing his mouth upon her breast." (Admin. Rec. App. A at 312.)

On June 16, 1997, Plaintiff pleaded nolo contendere to one misdemeanor count of sexual battery. (Admin. Rec. at 335.) At Plaintiff's plea and sentencing hearing before the Whitfield County Superior Court, the following exchange occurred:

> The Court: All right. You are charged, Dr. Patel, with sexual battery, and that is with making – intentionally making physical contact with the intimate parts of another person, [K.T.], without her consent, by placing your mouth upon her breast. As I understand it, she was a patient of yours. Did you do that?

Plaintiff: Yes.

The Court: Is that the truth?

Plaintiff: Yes.

(Admin. Rec. at 335.)

The Whitfield County Superior Court sentenced Plaintiff to eleven months and twenty-nine days of probation and a fine of $5,000. (Admin. Rec. App. A at 337.) The court also directed Plaintiff to perform 150 hours of community service and to pay a probation fee of $20 per month. (*Id.*) Finally, the court ordered Plaintiff to obtain an evaluation and treatment from a professional in the field of behavioral disorders. (*Id.*) Plaintiff was sentenced as a "first offender" under Georgia law. (*Id.*).

On July 11, 1997, the Georgia Board of Medical Examiners summarily suspended Plaintiff's Georgia medical license. (Admin. Rec. App. A. at 340-41.) In support of this suspension, the Georgia Board of Medical Examiners cited Plaintiff's conviction, as well as eight other complaints that the Georgia Board of Medical Examiners had received from female patients. (*Id.*) The Order of Summary Suspension provides that Plaintiff "placed his mouth on the breast of a female patient without the patient's consent." (*Id.*)

On October 1, 1997, Plaintiff entered into a consent order issued by the Georgia Board of Medical Examiners that required a two-year suspension of Plaintiff's medical license. (Admin. Rec. App. A at 319-28.) The consent order provided for all except six months of the suspension to be stayed if Plaintiff satisfied certain conditions. (*Id.*)

On November 7, 1997, Plaintiff entered into a stipulation with the Medical Board of California. (Admin. Rec. App. A. at 344-47.) Under this stipulation, Plaintiff surrendered his California medical license, which previously had been temporarily suspended. (*Id.*) The stipulation became effective on December 24, 1997. (*Id.* at 343.)

On December 2, 1997, Plaintiff's therapist certified to the Georgia Board of Medical Examiners that Plaintiff was fit to return to practice and that Plaintiff did not pose a threat to his patients. (Admin. Rec. App. B at 353.) The Georgia Board of Medical Examiners subsequently lifted the suspension of Plaintiff's Georgia medical license.

On June 12, 1998, the Inspector General for the Department of Health and Human Services ("Inspector General") notified Plaintiff that Plaintiff would be excluded from participating in Medicare, Medicaid, and other federally-funded programs for a minimum of five years, and that this period of exclusion could be increased based on aggravated [sic] factors. (June 12, 1998, letter.) On October 30, 1998, following Plaintiff's response to the June 12, 1998, letter, the Inspector General notified Plaintiff that the Inspector General had decided to exclude Plaintiff from participating in Medicaid, Medicare, and other federally-funded programs for a minimum of ten years, effective November 19, 1998. (Admin. Rec. App. A at 309-10.)

The Inspector General excluded Plaintiff from participating in federally-funded health care programs for a mandatory minimum five-year period. (Admin. Rec. App. A at 309.) The Inspector General based this decision on Plaintiff's conviction "of a criminal offense related to the neglect or abuse of patients in connection with the delivery

of a health care item or service." (*Id.*) The Inspector General increased Plaintiff's minimum period of exclusion to ten years based on evidence that Plaintiff had engaged in a non-consensual sexual act and a "continuing pattern of behavior," as well as on evidence that the Medical Board of California had revoked Plaintiff's license. (*Id.*)

Plaintiff requested administrative review of the Inspector General's determination by an Administrative Law Judge ("ALJ"). (Admin. Rec. App. A at 316.) On November 22, 1999, the ALJ affirmed the Inspector General's findings and upheld the ten-year exclusion. (Admin. Rec. Pt. 1 at 3.) In particular, the ALJ affirmed the mandatory minimum exclusion of five years, and found that the additional five-year exclusion was reasonable, even though the ALJ rejected that the Inspector General's conclusion that a pattern of sexual abuse existed. (Admin. Rec. Pt. 1 at 13-14.) In reaching this conclusion, the ALJ noted:

> The most persuasive evidence in this case is Petitioner's admission that he sexually abused a patient. . . . When an individual submits to an examination by a health care provider that individual is highly vulnerable to abusive conduct. In the normal course of the examination, the individual must submit to the most intimate conceivable scrutiny. The patient must rely on the provider's judgment and good faith. The doctor-patient relationship embodies a bond of trust that transcends all but the closest of personal relationships.
>
> I am aware that a ten-year exclusion is a very lengthy exclusion. However, I find it not to be unreasonable in light of the egregiousness of Petitioner's conduct and given even a slight

> possibility that such conduct might recur at some time in the future. A ten-year exclusion is reasonable given the way in which Petitioner breached his relationship of trust with K.T. Petitioner's actions might damage irretrievably the doctor-patient relationship between Petitioner and any of his patients. Petitioner's conduct towards K.T. suggests that others might be vulnerable if similarly situated. Given Petitioner's conduct, his continued participation in federally funded health care programs would be a legitimate reason for beneficiaries and recipients to suspect the integrity of both Petitioner and the programs themselves.

(Admin. Record Pt. 1 at 18-19.)

Plaintiff requested that the Departmental Appeals Board ("DAB") review the ALJ's decision. On July 14, 2000, the DAB affirmed the ALJ's decision, concluding that substantial evidence supported the ALJ's findings. (Admin. Record Pt. 1 at 41, 49.) The DAB's decision is the Secretary's final decision. 42 C.F.R. § 1005.21(j).

On September 19, 2000, Plaintiff filed this lawsuit. On April 23, 2000, [sic] Judge Brill issued her Report and Recommendation. Judge Brill recommends that this Court affirm the Secretary's final decision. Plaintiff has objected to Judge Brill's Report and Recommendation.[3]

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[3] Plaintiff's Objections state that Plaintiff "respectfully objects to all findings and conclusions in the Report [and Recommendation] which are adverse to him." (Pl.'s Obj. Report and Recommendation at 1.) Plaintiff's Objections, however, specifically address only Judge Brill's conclusion that the Inspector General properly applied the 1998 amendments to 42 C.F.R. § 1001.102(b) to Plaintiff's case. The Court

(Continued on following page)

III. Standard of Review

42 U.S.C.A. § 1320a-7(f) states, in relevant part:

> [A]ny individual or entity that is excluded (or directed to be excluded) from participation under this section is entitled to reasonable notice and opportunity for a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title, and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title, except that, in so applying such sections and section 405(l) of this title, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

42 U.S.C.A. § 1320a-7(f)(1). Under § 405(g), the Court must affirm the findings of fact made by the Secretary if "substantial evidence" supports those findings. 42 U.S.C.A. § 405(g).

"Substantial evidence is more than a scintilla, but less than a preponderance. It is such relevant evidence as a reasonable person would accept as adequate to support a conclusion." *Bloodsworth v. Heckler*, 703 F.2d 1233, 1239 (11th Cir. 1983); *see also Falge v. Apfel*, 150 F.3d 1320, 1322 (11th Cir. 1998) ("Substantial evidence is 'such

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thus concludes that Plaintiff's primary objection is to Judge Brill's determination that the inspector General properly applied the 1998 amendments to Plaintiff's case. In an abundance of caution, however, the Court also will address the other issues raised by Plaintiff on appeal.

relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'") (quoting *Richardson v. Perales,* 402 U.S. 389 (1971)). The Court "may not decide the facts anew, reweigh the evidence, or substitute [its] judgment for that of the [Commissioner]," even if the Court believes that "the evidence preponderates against the [Commissioner's] decision." *Bloodsworth*, 703 F.2d at 1239; *see also Wolfe v. Chater,* 86 F.3d 1072, 1076 (11th Cir. 1996) ("We should not reweigh the evidence nor should we substitute our discretion for that of the [Commissioner].").

The Court, however, does not apply a presumption of validity to the Secretary's application of the law. *Keeton v. Department of Health and Human Servs.,* 21 F.3d 1064, 1066 (11th Cir. 1994) (requiring Court to apply "close scrutiny" to Secretary's legal conclusion). The Secretary must "apply the correct law," and also must "provide the reviewing court with sufficient reasoning for determining that the proper legal analysis has been conducted." *Id.*

IV. Discussion

Plaintiff raised three primary issues on appeal: (1) whether the Secretary failed to show that the alleged abuse occurred in connection with Plaintiff's delivery of a health care service; (2) whether the Secretary improperly applied the October 1998 regulation to Plaintiff; and (3) whether the Secretary's decision to increase Plaintiff's exclusionary period by five years was arbitrary, capricious, or an abuse of discretion. The Court addresses those issues in turn.

A. Whether the Secretary has Demonstrated that the Alleged Abuse Occurred in Connection with Plaintiff's Delivery of a Health Care Service

42 U.S.C.A. § 1320a-7(a)(2) instructs the Secretary to exclude from participation in federally-funded healthcare programs "[a]ny individual or entity that has been convicted, under Federal or State law, of a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care service." 42 U.S.C.A. § 1320a-7(a)(2). 42 U.S.C.A. § 1320a-7(c)(3)(B) requires the Secretary to exclude such a person or entity from participation in federally-funded healthcare programs for a minimum period of five years. 42 U.S.C.A. § 1320a-7(c)(3)(B).

Plaintiff argues that the mandatory five-year exclusion does not apply to Plaintiff because the Secretary failed to prove all of the elements of 42 U.S.C.A. § 1320a-7(a)(2). Specifically, Plaintiff argues that the Secretary has not proven that the criminal offense for which Plaintiff pleaded nolo contendere occurred "in connection with the delivery of a health care item or service."

The Secretary relied upon a notarized statement submitted by K.T. to the Georgia Board of Medical Examiners to reach its conclusion that the offense to which Plaintiff pleaded nolo contendere occurred "in connection with the delivery of a health care item or service." Plaintiff complains that the Secretary may not rely on K.T.'s statement to establish the setting of Plaintiff's offense because the statement is unauthenticated, is uncorroborated, is hearsay, and is not part of the criminal record.

The Court agrees with Judge Brill's conclusion that Plaintiff's argument pertaining to K.T.'s statement is

without merit. As Judge Brill noted, the Secretary is not bound by the Federal Rules of Evidence (Report and Recommendation at 11; 42 U.S.C. § 405(b); 42 C.F.R. § 1005.17(b).) Further, hearsay is admissible in administrative hearings, and can constitute substantial evidence if it is reliable and credible. *J.A.M. Builders, Inc. v. Herman,* 233 F.3d 1350, 1354 (11th Cir. 2000). K.T.'s statement, when considered in the context of the record as a whole, is reliable and credible. The Secretary's finding that K.T.'s statement provided credible and reliable evidence thus is well-supported by the record, and substantial evidence supports the Secretaries' determination upholding Plaintiff's five-year mandatory exclusion under 42 U.S.C.A. § 1320a-7(a).

B. Whether the October 1998 Regulation Applies to Plaintiff

Next, Plaintiff argues that the Inspector General erred in extending Plaintiff's exclusion from federally-funded programs for five additional years. According to Plaintiff, the Inspector General improperly applied a regulation that did not become effective until October 2, 1998. Plaintiff's nolo contendere plea, however, occurred in 1997, and the Inspector General first sent correspondence to Plaintiff concerning his exclusion in June 1998. Plaintiff therefore argues that applying the October 1998 regulation to Plaintiff's case had an impermissibly retroactive effect.

a. The Regulation

In 1992, the Secretary promulgated 42 C.F.R. § 1001.102(b), which set forth factors for determining the

length of exclusions to be imposed under 42 U.S.C.A. § 1320a-7. The 1992 version of 42 C.F.R. § 1001.102(b) (the "1992 regulation") provided, in relevant part:

> any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion [beyond five years] . . .
>
> (3) The acts that resulted in the conviction, or similar acts, had a significant adverse physical, mental or financial impact on one or more program beneficiaries or other individuals; [or]
>
> (6) the convicted individual or entity has a prior criminal, civil or administrative sanction record; . . . .

42 C.F.R. § 1001.102(b) (1992).

In 1997, the Secretary published several proposed changes to 42 C.F.R. § 1001.102(b) in the Federal Register. 62 Fed. Reg. 47182 (Sept. 8, 1997). The Secretary later adopted those proposed changes, with slight modifications. 62 Fed. Reg. 46676 (Sept. 2, 1998). On October 2, 1998, the amended version of 42 C.F.R. § 1001.102(b) (the "October 1998 regulation") became effective. *Id.*) [sic]

In October 1998 regulation provides, as modified and in relevant part:

> Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion – . . .
>
> (3) The acts that resulted in the conviction, or similar acts, had a significant adverse physical, mental or financial impact on

one or more program beneficiaries or other individuals;

. . .

(4) In convictions involving patient abuse or neglect, the action that resulted in the conviction was premeditated, was part of a continuing pattern of behavior, or consisted of non-consensual sexual acts;

. . .

(9) Whether the individual or entity was convicted of other offenses besides those which formed the basis for the exclusion, or has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for imposition of the exclusion.

42 C.F.R. § 1001.102(b) (2001).[4]

b. Whether the October 1998 Regulation Has a Retroactive Effect

Plaintiff argues that the October 1989 [sic] regulation, as applied to his case, has an impermissible retroactive effect. "Retroactivity is not favored in the law." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). "Thus,

[4] As originally published, the final quoted factor was labeled § 1001.102(b)(8). After subsequent changes, that factor was designated as § 1001.102(b)(9). Many of the documents in the record refer to the factors as § 1001.102(b)(8).

congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result." *Id.* "By the same principle, a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms." *Id.* Congress has not granted such power to the Department of Health and Human Resources [sic] in connection with the Medicare Act. *Id.* at 213-14. The Secretary therefore cannot apply the October 1998 regulation to Plaintiff if the October 1998 regulation has a retroactive effect.

"While statutory retroactivity has long been disfavored, deciding when a statute operates 'retroactively' is not always a simple or mechanical task." *Landgraf v. USI Film Prods.*, 511 U.S. 244, 268 (1994). "Any test of retroactivity will leave room for disagreement in hard cases, and is unlikely to classify the enormous variety of legal changes with perfect philosophical clarity." *Id.* at 270. "However, retroactivity is a matter on which judges tend to have 'sound . . . instinct[s],' . . . and familiar considerations of fair notice, reasonable reliance, and settled expectations offer sound guidance." *Id.* (alteration in original) (citation omitted).

The Supreme Court has indicated that " 'every statute, which takes away or impairs vested rights acquired under existing laws, or creates a new obligation, imposes a new duty, or attaches a new disability, in respect to transactions or considerations already past, must be deemed retrospective.' " *Landsgraf*, 511 U.S. at 269 (quoting *Society for Propagation of the Gospel v. Wheeler*, 22 F. Cas. 756, 766-69 (C.C.N.H. 1814) (No. 13,156)). However, "[a] statute does not operate 'retrospectively' merely because it

is applied in a case arising from conduct antedating the statute's enactment, or upsets expectations based in prior law." *Id.* (citation omitted). "Rather, the court must ask whether the new provision attaches new legal consequences to events completed before its enactment." *Id.* at 269-70. "The conclusion that a particular rule operates 'retroactively' comes at the end of a process of judgment concerning the nature and extent of the change in the law and the degree of connection between the operation of the new rule and a relevant past event." *Id.* at 270.

For the following reasons, the Court concludes that the October 1998 regulation is not retroactive in effect. First, the October 1998 regulation does not sanction conduct that was lawful when it occurred. Instead, the October 1998 regulation simply applies to conduct already sanctioned by the 1992 version of the regulation. This factor diminishes concerns about lack of notice.

Second, the October 1998 regulation does not have a retributive purpose. Instead, the basic purpose of 42 U.S.C.A. § 1320a-7 the statute under which the Secretary promulgated the October 1998 regulation, is "to improve the ability of the Secretary and the Inspector General of [HHS] to protect Medicare, Medicaid, [and other social services programs] from fraud and abuse, and to protect the beneficiaries of those programs from incompetent practitioners and from inappropriate or inadequate care." *Manocchio v. Kusserow*, 961 F.2d 1539, 1541 (11th Cir. 1992) (alterations in original) (quoting S. Rep. No. 109, 100th Cong., 1st Sess. 1-2 (1987), *reprinted in* 1987 U.S.C.C.A.N. 682). The primary goal of 42 U.S.C.A. § 1320a-7 "is to protect present and future Medicare beneficiaries from the abusers of these programs." *Id.* at 1542. The October 1998 regulation, which implements 42

U.S.C.A. § 1320a-7, thus is remedial, rather than punitive. *Id.* Consequently, the October 1998 regulation "is not in a category in which objections to retroactive application on grounds of fairness have their greatest force." *Landgraf*, 511 U.S. at 282.

Third, *Landgraf* does not compel a finding that the October 1998 regulation is retroactive. *Landgraf* involved the 1991 amendments to Title VII of the Civil Rights Act of 1964, which created a right to recover compensatory and punitive damages for employment discrimination, and which authorized a jury trial. *Landgraf*, 511 U.S. at 247. In *Landgraf*, the Supreme Court ultimately found that applying the 1991 amendments to the pending case was improper, because applying the 1991 amendments would create an impermissible retroactive effect. *Id.* at 286.

Here, the October 1998 regulation is not "quintessentially backward looking," and does not affect the monetary liabilities of affected healthcare providers. *Landgraf*, 511 U.S. at 282. Instead, the October 1998 regulation, as applied, excludes providers from *future* participation in federally-funded programs.

Further, the October 1998 regulation does not implicate any of the concerns typically associated with retroactive legislation. The 1992 regulation afforded the Secretary discretion to impose a term of exclusion that exceeded five years. 42 C.F.R. § 1001.102(b) (1992). The Secretary could have found that an increase in the term of exclusion was warranted for Plaintiff because the acts that resulted in Plaintiff's nolo contendere plea "had a

significant adverse physical, mental or financial impact" on K.T. 42 C.F.R. § 1001.102(b)(3).[5]

Additionally, the October 1998 regulation was intended to clarify the 1992 regulation and "to help distinguish between more egregious and less egregious cases involving patient abuse." 62 Fed. Reg. 47185 (Sept. 8, 1997). The history of the October 1998 regulation does not indicate an intent to make a significant change in the way that the Secretary made discretionary decisions. Instead, the factors added by the October 1998 regulation simply afford [sic] the Secretary to exercise its existing discretion more carefully and accurately.

For the reasons discussed above, the Court concludes that the October 1998 regulation does not have an impermissible retroactive effect on Plaintiff. The Court therefore rejects Plaintiff's second argument.

C. Whether the Imposition of a Ten-Year Period of Exclusion Was Not Arbitrary, Capricious, or an Abuse of Discretion

Finally, Plaintiff argues that even if the October 1998 regulation applied to Plaintiff's case, the decision to lengthen Plaintiff's exclusion by an additional five years was arbitrary, capricious, and an abuse of discretion. As an initial matter, the Court observes that the appropriate standard of review of the Secretary's decision is the

[5] The Secretary did not rely upon this factor of the 1992 regulation to enhance Plaintiff's period of exclusion. The Court finds, however, that ample evidence in the record would have supported an enhanced exclusion under this factor of the 1992 regulation.

standard set forth in 42 U.S.C.A. § 405(g). That standard requires the Court to determine that the Secretary engaged in "reasoned decision making." *Owens v. Heckler*, 748 F.2d 1511, 1514 (11th Cir. 1984). The Court, however, may not reweigh the evidence or substitute its judgment for that of the Secretary. *Bloodsworth*, 703 F.2d at 1239.

Plaintiff initially contends that one of the factors on which the Secretary relied to increase Plaintiff's exclusion to five years does not apply to Plaintiff. The factor cited by the Secretary states that the Secretary may consider:

> Whether the individual or entity was convicted of other offenses besides that which formed the basis for the exclusion, or has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for imposition of the exclusion.

42 C.F.R. § 1001.102(b)(9) (2001). According to Plaintiff, the Secretary improperly based its application of this factor on the actions taken by the California Medical Board against Plaintiff. Plaintiff argues that a second adverse action taken against him based on the same facts cannot support application of this factor.

Plaintiff's argument, however, is contrary to the plain language of 42 C.F.R. § 1001.102(b)(9), which requires that the adverse action be based on the same set of circumstances used to support the imposition of an exclusion. 42 C.F.R. § 1001.102(b)(9). The Court further finds that the passage of the Federal Register cited by Plaintiff, when considered in context, does not support Plaintiff's position. 63 Fed. Reg. 46680-81 (Sept. 2, 1998). Instead, the Federal

Register passage and 42 C.F.R. § 1001.102(b)(9) indicate that it is appropriate for the Secretary to consider multiple adverse actions taken against Plaintiff that are based on the same underlying misconduct.

Next, Plaintiff contends that the Secretary improperly applied 42 C.F.R. § 1001.102(b)(3) to increase Plaintiff's period of exclusion. 42 C.F.R. § 1001.102(b)(3), which now is codified at 42 C.F.R. § 1001.102(b)(4), states that the Secretary should consider:

> In convictions involving patient abuse or neglect, the action that resulted in the conviction was premeditated, was part of a continuing pattern of behavior, or consisted of non-consensual sexual acts.

42 C.F.R. § 1001.102(b)(4). Plaintiff argues that a single isolated case of misdemeanor sexual battery cannot support an increased exclusion under the "non-consensual sexual acts" portion of this regulation. The Court, however, agrees with Judge Brill that the Secretary's decision to increase Plaintiff's period of exclusion for five years based on this provision was not unreasonable and was not without foundation.

D. Summary

In sum, the Court rejects all of the issues raised by Plaintiff on appeal. The Court finds that substantial evidence exists to support the Secretary's determination. The Court therefore affirms the Secretary's final determination and adopts the Report and Recommendation.

V. Conclusion

ACCORDINGLY, the Court **ADOPTS** the Report and Recommendation of United States Magistrate Judge Gerrilyn G. Brill [23], and **AFFIRMS** the Secretary's final decision. The Court **GRANTS** Plaintiff's Motion to Supplement the Administrative Record [16], **DENIES** Plaintiff's Motion to Supplement the Administrative Record [17], **OVERRULES** Plaintiff's Objections to the Report and Recommendation [24], and **SUSTAINS** Defendants' Response to Plaintiffs' [sic] Objections to the Report and Recommendation [27]. The Court **DIRECTS** the Clerk to **CLOSE** this case.

IT IS SO ORDERED, this the 2nd day of July, 2002.

/s/ Harold Murphy
UNITED STATES
DISTRICT JUDGE

RULES and REGULATIONS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1001, 1002, 1003, 1004, 1005, 1006 and 1007

RIN 0991-AA47

Health Care Programs: Fraud and Abuse; Amendments to OIG Exclusion and CMP Authorities Resulting From Public Law 100-93

Wednesday, January 29, 1992

AGENCY: Office of Inspector General, HHS.

ACTION: Final rule.

SUMMARY: This final rule implements the OIG sanction and civil money penalty provisions established through section 2 and other conforming amendments in the Medicare and Medicaid Patient and Program Protection Act of 1987, along with certain additional provisions contained in the Consolidated Omnibus Budget Reconciliation Act of 1985, the Omnibus Budget Reconciliation Act (OBRA) of 1987, the Medicare Catastrophic Coverage Act of 1988, OBRA of 1989, and OBRA of 1990. Specifically, these regulations are designed to protect program beneficiaries from unfit health care practitioners, and otherwise to improve the anti-fraud provisions of the Department's health care programs under titles V, XVIII, XIX and XX of the Social Security Act.

EFFECTIVE DATE: These regulations are effective on January 29, 1992.

FOR FURTHER INFORMATION CONTACT:

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James Patton, Office of Investigations, (301) 966-9601.

Robin Schneider, Office of the General Counsel (202) 619-1306.

* * *

Subpart B – Mandatory Exclusions

§ 1001.101 Basis for liability.

The OIG will exclude any individual or entity that –

(a) Has been convicted of a criminal offense related to the delivery of an item or service under Medicare or a State health care program, including the performance of management or administrative services relating to the delivery of items or services under any such program, or

(b) Has been convicted, under Federal or State law, of a criminal offense related to the neglect or abuse of a patient, in connection with the delivery of a health care item or service, including any offense that the OIG concludes entailed, or resulted in, neglect or abuse of patients. The conviction need not relate to a patient who is a program beneficiary.

§ 1001.102 Length of exclusion.

(a) No exclusion imposed in accordance with § 1001.101 will be for less than 5 years.

(b) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion –

(1) The acts resulting in the conviction, or similar acts, resulted in financial loss to Medicare and the State health care programs of $1,500 or more. (The entire amount of financial loss to such programs will be considered, including any amounts resulting from similar acts not adjudicated, regardless of whether full or partial restitution has been made to the programs);

(2) The acts that resulted in the conviction, or similar acts, were committed over a period of one year or more;

(3) The acts that resulted in the conviction, or similar acts, had a significant adverse physical, mental or financial impact on one or more program beneficiaries or other individuals;

(4) The sentence imposed by the court included incarceration;

(5) The convicted individual or entity has a prior criminal, civil or administrative sanction record; or

(6) The individual or entity has at any time been overpaid a total of $1,500 or more by Medicare or State health care programs as a result of improper billings.

(c) Only if any of the aggravating factors set forth in paragraph (b) of this section justifies an exclusion longer than 5 years, may mitigating factors be considered as a basis for reducing the period of exclusion to no less than 5 years. Only the following factors may be considered mitigating –

(1) The individual or entity was convicted of 3 or fewer misdemeanor offenses, and the entire amount of financial loss to Medicare and the State health care programs due to the acts that resulted in the conviction, and similar acts, is less than $1,500;

(2) The record in the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional or physical condition before or during the commission of the offense that reduced the individual's culpability; or

(3) The individual's or entity's cooperation with Federal or State officials resulted in –

(i) Others being convicted or excluded from Medicare or any of the State health care programs, or

(ii) The imposition against anyone of a civil money penalty or assessment under part 1003 of this chapter.

[Code of Federal Regulations]
[Title 42, Volume 3, Parts 430 to end]
[Revised as of October 1, 1998]
From the U.S. Government Printing Office via GPO Access
[**CITE: 42CFR1001.101**]

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TITLE 42 – PUBLIC HEALTH

HUMAN SERVICES

PART 1001 – PROGRAM INTEGRITY – MEDICARE AND STATE HEALTH CARE PROGRAMS –

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Subpart B – Mandatory Exclusions

Sec. 1001.**101** Basis for liability.

The OIG will exclude any individual or entity that –

(a) Has been convicted of a criminal offense related to the delivery of an item or service under Medicare or a State health care program, including the performance of management or administrative services relating to the delivery of items or services under any such program;

(b) Has been convicted, under Federal or State law, of a criminal offense related to the neglect or abuse of a patient, in connection with the delivery of a health care item or service, including any offense that the OIG concludes entailed, or resulted in, neglect or abuse of patients (the delivery of a health care item or service includes the provision of any item or service to an individual to meet his or her physical, mental or emotional needs or well-being, whether or not reimbursed under Medicare, Medicaid or any Federal health care program);

(c) Has been convicted, under Federal or State law, of a felony that occurred after August 21, 1996 relating to

fraud, theft, embezzlement, breach of fiduciary responsibility, or other misconduct –

(1) In connection with the delivery of a health care item or service, including the performance of management or administrative services relating to the delivery of such items or services, or

(2) With respect to any act or omission in a health care program (other than Medicare and a State health care program) operated by, or financed in whole or in part, by any Federal, State or local government agency; or

(d) Has been convicted, under Federal or State law, of a felony that occurred after August 21, 1996 relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, as defined under Federal or State law. This applies to any individual or entity that –

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(1) Is, or has ever been, a health care practitioner, provider or supplier;

(2) Holds, or has held, a direct or indirect ownership or control interest (as defined in section 1124(a)(3) of the Act) in an entity that is a health care provider or supplier, or is, or has ever been, an officer, director, agent or managing employee (as defined in section 1126(b) of the Act) of such an entity; or

(3) Is, or has ever been, employed in any capacity in the health care industry.

[63 FR 46686, Sept. 2, 1998]

Effective Date Note: At 63 FR 46686, Sept. 2, 1998, Sec. 1001.**101** was revised, effective Oct. 2, 1998. For the convenience of the user, the superseded text is set forth as follows:

Sec. 1001.**101** Basis for liability.

The OIG will exclude any individual or entity that –

(a) Has been convicted of a criminal offense related to the delivery of an item or service under Medicare or a State health care program, including the performance of management or administrative services relating to the delivery of items or services under any such program, or

(b) Has been convicted, under Federal or State law, of a criminal offense related to the neglect or abuse of a patient, in connection with the delivery of a health care item or service, including any offense that the OIG concludes entailed, or resulted in, neglect or abuse of patients. The conviction need not relate to a patient who is a program beneficiary.

Subpart B – Mandatory Exclusions

Sec. 1001.**102** Length of exclusion.

(a) No exclusion imposed in accordance with Sec. 1001.101 will be for less than 5 years.

(b) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion –

(1) The acts resulting in the conviction, or similar acts, resulted in financial loss to a government program or to one or more entities of $1,500 or more. (The entire

amount of financial loss to such programs or entities, including any amounts resulting from similar acts not adjudicated, will be considered regardless of whether full or partial restitution has been made);

(2) The acts that resulted in the conviction, or similar acts, were committed over a period of one year or more;

(3) The acts that resulted in the conviction, or similar acts, had a significant adverse physical, mental or financial impact on one or more program beneficiaries or other individuals;

(4) In convictions involving patient abuse or neglect, the action that resulted in the conviction was premeditated, was part of a continuing pattern or behavior, or consisted of non-consensual sexual acts;

(5) The sentence imposed by the court included incarceration;

(6) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing;

(7) The individual or entity has at any time been overpaid a total of $1,500 or more by Medicare, Medicaid and all other Federal health care programs, or other third-party payers, as a result of improper billings; or

(8) Whether the individual or entity was convicted of other offenses besides those which formed the basis for the exclusion, or has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of

circumstances that serves as the basis for imposition of the exclusion.

(c) Only if any of the aggravating factors set forth in paragraph (b) of this section justifies an exclusion longer than 5 years, may mitigating factors be considered as a basis for reducing the period of exclusion to no less than 5 years. Only the following factors may be considered mitigating –

(1) The individual or entity was convicted of 3 or fewer misdemeanor offenses, and the entire amount of financial loss to Medicare and the State health care programs due to the acts that resulted in the conviction, and similar acts, is less than $1,500;

(2) The record in the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional or physical condition before or during the commission of the offense that reduced the individual's culpability; or

(3) The individual's or entity's cooperation with Federal or State officials resulted in –

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(i) Others being convicted or excluded from Medicare, Medicaid and all other Federal health care programs,

(ii) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or

(iii) The imposition against anyone of a civil money penalty or assessment under part 1003 of this chapter.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46686, Sept. 2, 1998]

Effective Date Note: At 63 FR 46686, Sept. 2, 1998, Sec. 1001.**102** was amended by revising paragraph (b); republishing introductory paragraph (c); and revising paragraph (c)(3), effective Oct. 2, 1998. For the convenience of the user, the superseded text is set forth as follows:

Sec. 1001.**102** Length of exclusion.

* * *

(b) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion –

(1) The acts resulting in the conviction, or similar acts, resulted in financial loss to Medicare and the State health care programs of $1,500 or more. (The entire amount of financial loss to such programs will be considered, including any amounts resulting from similar acts not adjudicated, regardless of whether full or partial restitution has been made to the programs);

(2) The acts that resulted in the conviction, or similar acts, were committed over a period of one year or more;

(3) The acts that resulted in the conviction, or similar acts, had a significant adverse physical, mental or financial impact on one or more program beneficiaries or other individuals;

(4) The sentence imposed by the court included incarceration;

(5) The convicted individual or entity has a prior criminal, civil or administrative sanction record; or

(6) The individual or entity has at any time been overpaid a total of $1,500 or more by Medicare or State health care programs as a result of improper billings.

(c) * * *

(3) The individual's or entity's cooperation with Federal or State officials resulted in –

(i) Others being convicted or excluded from Medicare or any of the State health care programs, or

(ii) The imposition against anyone of a civil money penalty or assessment under part 1003 of this chapter.